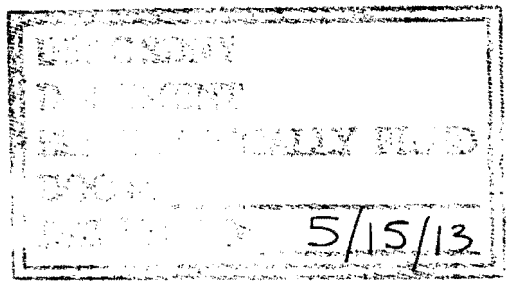

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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MEDISIM LTD.,

Plaintiff,

- against -

BESTMED LLC,

Defendant.

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OPINION AND ORDER

10 Civ. 2463 (SAS)

SHIRA A. SCHEINDLIN, U.S.D.J.:

I. INTRODUCTION

This is an action for the infringement of a patent for a non-invasive thermometer. The case was tried to a jury, which returned a verdict finding that defendant BestMed LLC ("BestMed") willfully infringed on U.S. Patent No. 7,597,668 ("the '668 Patent"), of which plaintiff Medisim Ltd. ("Medisim") is the sole assignee and owner. The jury also found that BestMed infringed Medisim's copyright in the Instructions for Use ("IFU") for its thermometers, and that BestMed was unjustly enriched under New York law. The jury awarded Medisim $1.2 million for its patent infringement claim, and $2.29 million for its unjust enrichment claim. Medisim sought only equitable relief for its copyright claim.

Presently before the Court is BestMed's post-trial motion for judgment as a matter of law ("JMOL"), or, alternatively, for a new trial. BestMed asserts the following grounds in support of its motion: (1) the '668 Patent is invalid (on four theories); (2) BestMed did not infringe on the '668 Patent, directly or indirectly; (3) there was insufficient evidence of willful infringement; (4) BestMed is not liable for unjust enrichment under New York law; and (5) Medisim is not entitled to damages. Also pending are three motions brought by Medisim, seeking, respectively, a permanent injunction and disposition of infringing materials, post-trial relief, and a judicial finding of willful infringement.

Although this case was expansive when opening arguments began, it narrowed substantially prior to the jury's deliberations. Specifically, the evidence presented at trial narrowed the anticipation inquiry to the question of whether the prior art FHT-1 thermometer meets the 'deep tissue temperature' limitation of the '668 Patent. The jury's verdict of no anticipation implicitly answered this question in the negative. However, the evidence presented at trial clearly and convincingly demonstrates that the FHT-1 calculates 'deep tissue temperature,' and no reasonable jury could have found otherwise. Therefore, BestMed's motion for JMOL on anticipation is granted.

Similarly, Medisim's claim for unjust enrichment was narrowed

substantially prior to its submission to the jury. Because substantial evidence does not support the jury's verdict awarding damages to Medisim for unjust enrichment, JMOL on unjust enrichment is granted. Finally, Medisim's pending motions are denied, save for its motion for an injunction disposing of materials infringing its copyright, which is granted.

II. BACKGROUND[1]

BestMed's motion for a JMOL of invalidity and non-infringement turns entirely on an exceedingly narrow issue: whether the FHT-1 thermometer, a non-invasive temple thermometer sold by Medisim more than one year prior to the effective date of the '668 Patent, meets the deep tissue temperature limitation of the '668 Patent.[2] When placed in its proper context, it is plain that this issue must be resolved in BestMed's favor.

Providing the proper context is a difficult undertaking in light of this

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[1] The facts of this case have been recited in numerous opinions over the course of this litigation. *See, e.g., Medisim Ltd. v. BestMed LLC* (the "S.J. Op."), No. 10 Civ. 2463, – F. Supp. 2d –, 2012 WL 5954757, at *1 (S.D.N.Y. Nov. 28, 2012) (ruling on the parties' cross motions for summary judgment). Familiarity with these prior opinions is assumed.

[2] "FHT" means "forehead thermometer," and the designation refers to Medisim's line of non-invasive (or semi-invasive, *e.g.*, armpit) thermometers. *See* Trial Transcript ("Tr.") (Direct Examination of Moshe Yarden ("Yarden Direct")) at 106:9. Medisim also had a line of invasive thermometers, which are designated M5T. *See id*. (Cross-Examination of Stanley Cohen ("Cohen Cross")) at 745:14-19.

case's technical complexity, thorny procedural history, and voluminous trial record. Moreover, when considering a post-trial motion for JMOL, a court must take the utmost care not to impinge upon the vital role of the jury in our judicial system. For these reasons, although the material question in this case is narrow and readily resolved, it is necessary to provide a detailed recitation of the facts relevant to validity and infringement.

The section below therefore recites a full account of the facts, beginning with the Court's claim construction, and ending with the evidence adduced at trial. It then summarizes the facts relevant to BestMed's motion to set aside the verdict of unjust enrichment.

A. Claim Construction

The '668 Patent was filed on May 31, 2006 and issued on October 6, 2009 to Moshe Yarden, one of Medisim's founding partners.[3] It incorporates by reference an earlier patent, U.S. Patent No. 6,280,397 ("the '397 Patent"), which was issued on August 28, 2001. The '397 Patent names Yarden as a co-inventor, and is also assigned to Medisim.[4]

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[3] *See* Stipulation of Undisputed Facts ("Stip. Facts"), Ex. A to Joint Pre-Trial Order, ¶¶ 2; 8.

[4] *See Medisim Ltd. v. BestMed LLC* (the "*Markman* Op."), No. 10 Civ. 2463, 2011 WL 2693896, at *1 (S.D.N.Y. July 8, 2011).

The '668 Patent is titled "Non-Invasive Temperature Measurement." As this title suggests, the claimed invention relates to a non-invasive thermometer. The '668 Patent contains two independent claims: an apparatus claim and a method claim. Claim 1, the independent *apparatus* claim, states:

> A thermometric device, comprising:
>
> a probe, comprising:
>
> a membrane configured to be applied to an external surface of a body of a subject; and
>
> one or more temperature sensors located within the probe in thermal contact with the membrane; and
>
> a processing unit configured to receive a plurality of temperature readings from the one or more temperature sensors, to determine time-dependent parameters of temperature change responsively to the plurality of temperature readings *to calculate, a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors*, and to calculate a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.[5]

In my *Markman* Order, I gave the following constructions to the disputed terms in Claim 1:

> "Probe" means "portion of thermometer including a membrane

[5] '668 Patent at col. 10:1-18 (emphasis added to demarcate the "deep tissue temperature" limitation).

and one or more temperature sensors that touches the exterior skin."

"Membrane" means "a layer or sheet of material."

"One or more temperature sensors" means "one or more thermistor or resistance temperature defectors (RTDs), or any form of thermistor, temperature sensor, or thermocouple."

"Configured to receive a plurality of temperature readings from the one or more temperature sensors" means "configured to receive temperature readings, at least one of which comes from the external body surface, from one or more temperature sensors."

"Time-dependent parameters of temperature change," means "multiple values of temperature change that vary with time and that are taken at different times."

"To calculate" [means] "using a computation to estimate, approximate, predict or determine."

"Core body temperature" [means] "the temperature of blood in the pulmonary artery."[6]

The independent *method* claim of the '668 Patent, Claim 21, states:

A method for thermometric measurement, comprising:

> applying a probe, which comprises a heat-conducting membrane and one or more temperature sensors in thermal communication with the membrane, to an external surface of a body of a subject;
>
> receiving a plurality of temperature readings from the one or more temperature sensors while the probe is applied to

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[6] *Markman* Op., 2011 WL 2693896, at *11 (quoting '668 Patent at col. 10:1-18).

> the surface of the body;
>
> determining time-dependent parameters of temperature change responsively to the plurality of temperature readings;
>
> calculating a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors; and calculating a core body temperature by correcting for a difference between the core body temperature and the deep tissue temperature.[7]

My *Markman* order construed Claim 21 as follows: "the user is 'applying a probe . . . to an external surface,' while the processing unit is 'receiving a plurality of temperature readings'; 'determining time-dependent parameters of temperature change'; 'calculating a deep tissue temperature' and 'calculating a core body temperature.'"[8]

B. The Deep Tissue Temperature Limitation

The only dispute as to anticipation is whether the FHT-1 meets the deep tissue limitation of the '668 Patent.[9] This section sets forth the facts of record

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[7] '668 Patent at col. 11:25-41.

[8] *Markman* Op., 2011 WL 2693896, at *11 (quoting '668 Patent at col. 11:25-41).

[9] *See* BestMed's Memorandum in Support of Its Motion for JMOL or, Alternatively, for a New Trial ("Def. Mem.") at 2; Memorandum in Support of Medisim's Opposition to BestMed's Motion for JMOL, or, Alternatively for a New Trial ("Opp. Mem.") at 3-4.

relevant to this limitation, including: (1) the intrinsic evidence; (2) the procedural history; and (3) the evidence presented at trial.

1. Intrinsic Evidence

a. Claim Construction

i. "Deep Tissue Temperature"

Medisim advanced the following construction of "deep tissue temperature" in its *Markman* brief: "stable temperature under the skin that is minimally affected by external factors and is the source of heat conducted to the one or more sensors."[10] BestMed advanced the construction that "deep tissue temperature" means "a heat source below the skin."[11] At the *Markman* hearing, though, the parties agreed that the term did not need to be construed,[12] and I subsequently declined to construe it.[13]

The litigation therefore proceeded on the assumption that "deep tissue temperature" was to be given its plain and ordinary meaning in the context of the

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[10] 3/4/11 Plaintiff's Opening Claim Construction Brief, Doc. No. 33, at 15.

[11] 3/4/11 Opening Claim Construction Brief by BestMed ("Def. *Markman* Br."), Doc. No. 34, at 18.

[12] *See* 4/28/11 Hearing Transcript at 108:18-19.

[13] *See Markman* Op., 2011 WL 2693896, at *9.

intrinsic evidence.[14] There is no dispute that, in the '668 Patent, the term "deep tissue temperature" "reflects" the "temperature at a location under the skin that is the source of heat conducted to the sensors in the probe. . . ."[15]

Two points follow directly from this construction of "deep tissue temperature." *First*, plainly, the "source of heat" that causes the measured "temperature at a location under the skin" will vary depending upon where the probe is applied. For example, if the probe were applied to the temple, the source of heat would be the temporal artery, and the deep tissue temperature would therefore approximate this temperature. *Second*, "deep tissue temperature" (also called "local temperature" in the '668 Patent) is distinct from "surface temperature," *i.e.*, the temperature of the exterior skin, and from "core temperature," *i.e.* the temperature of the pulmonary artery.

ii. The Deep Tissue Temperature Limitation

During *Markman* proceedings, BestMed contended that the deep tissue temperature limitation — as opposed to the phrase "deep tissue temperature"

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[14] *See Biogen Idec, Inc. v. GlaxoSmithKline LLC*, No. 2012-1120, – F.3d –, 2013 WL 1603360, at *4 (Fed. Cir. Apr. 16, 2013) ("[A] term's ordinary meaning must be considered in the context of all the intrinsic evidence, including the claims, specification, and prosecution history.") (citations omitted).

[15] '668 Patent at col. 2:3-5. *See* Tr. (Medisim Summation) at 1617:20-22 ("And the parties agreed that local or deep tissue temperature is the temperature, the heat under the skin, that's not in dispute.").

in isolation — is a means-plus-function claim under Title 35 of the United States Code, Section 112, ¶ 6. Specifically, BestMed argued that although the limitation does not use the catch-word "means," it nevertheless employs means-plus-function claiming, because the only structure that the '668 Patent discloses is a generic "processing unit," and the only method it discloses for calculating a deep tissue temperature is the '397 algorithm.[16] Based on this argument, BestMed offered the following construction of the limitation: "[t]he microprocessor calculates the temperature of a heat source below the skin's surface according to the algorithm set forth in [the '397 Patent at col. 1:1-58-col. 2:1-57 (the "'397 algorithm")]."[17]

Because of the presumption against means-plus-function claiming created by the absence of the word "means," and because the specification of the '668 Patent disclosed sufficient structure, I did not construe the deep tissue temperature limitation as a means-plus-function claim.[18] This ruling resolved *sub silentio* BestMed's argument that the '668 Patent did not disclose sufficient

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[16] *See id*. at 19-21.

[17] Def. *Markman* Br. at 19.

[18] *See Markman* Op., 2011 WL 2693896, at *10 ("In light of the strong presumption against applying § 112, ¶ 6 and this claim language, I find that 'processing unit' connotes a sufficiently definite structure to a person of ordinary skill in the art to avoid § 112, ¶ 6 treatment.") (citing *Inventio AG v. ThyssenKrupp Elevator Americas Corp.*, 649 F.3d 1350, 1360 (Fed. Cir. 2011)).

structure to calculate a deep tissue temperature by any means other than through the '397 algorithm,[19] an argument properly addressed to enablement, not the analysis of means-plus-function claiming.

b. Deriving Deep Tissue Temperature

Although the parties agree on the construction of the term deep tissue temperature, they dispute how that temperature is derived. The intrinsic evidence sheds some light on this dispute. The '668 Patent indicates that deep tissue temperature may be derived from the heat-flux algorithm of the '397 Patent, and discloses an embodiment in which a two-sensor probe applied to an external body surface uses the output of the '397 Patent in conjunction with an empirically derived formula to determine the user's core body temperature. Moreover, the prosecution history of the '668 Patent estops Medisim from denying that a user's deep tissue temperature may be derived from an infrared thermometer applied to the user's forehead.

i. The '668 Patent

The '668 Patent states that "[t]he thermometer is configured to perform the heat flux calculation [*e.g.*, an algorithm similar, or identical, to that

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[19] Def. *Markman* Br. at 20 ("The '668 Patent teaches no algorithm for calculating deep tissue temperature, except vis-a-vis the '397 Patent . . . . Thus, the subject claim phrase is subject to §112, ¶ 6, and should be construed as limited to the '397 Patent algorithm.").

disclosed in the '397 Patent] so as to derive a value of the [] [deep tissue] temperature."[20] In particular, the '668 Patent discloses an embodiment in which,

> [u]sing the heat flux algorithm described in the . . . ['397 Patent], the processing unit calculates from the temperature readings a local temperature. The local temperature, also referred to as a deep tissue temperature, reflects a temperature at a location under the skin that is the source of heat conducted to the sensors in the probe.[21]

The '668 Patent teaches that a reliable approximation of core temperature may be derived from a measurement of the skin's surface temperature if this temperature is first converted to an approximation of deep tissue temperature. It states that:

> The local temperature determined by the '397 algorithm is less affected than the surface temperature at the measurement site is [by] external factors such as ambient temperature and humidity. The local temperature is also less subject to variations in the body's heat regulation at the body's extremities. Consequently, there is a closer correlation between local temperature and core body temperature than there is between surface temperature and core body temperature.[22]

The Appendix of the '668 Patent (the "Appendix") teaches that the '397 Patent "provides a method for rapidly determining a core body temperature based on heat flux through a thermometer when the thermometer is inserted into an

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[20] '668 Patent at col. 2:6-7.

[21] *Id*. at col. 6:55-62.

[22] *Id*. at col. 7:1-8.

orifice of the body."[23] The '668 Patent further states that "[t]he accuracy of the derived temperature of [the '397 patent] is diminished when temperature measurements are made at an external measurement site on the body[,]" and goes on to provide an embodiment of the claimed invention in which "an empirically derived formula is used by the processing unit to determine core body temperature based on temperature readings made by sensors within the probe when the probe is applied to an external body surface."[24]

It is necessary to summarize this formula in order to properly evaluate BestMed's anticipation contentions. The inputs to the formula are "temperature readings from two sensors: a first sensor positioned at a shorter thermal distance from the thermometer membrane, and a second sensor at a farther distance."[25] In the exemplary embodiment disclosed by the Appendix, these temperature readings are taken ten times at 0.4 seconds intervals.[26]

The formula comprises nine constants, each used only once, and six variables. It is the sum of nine terms: (1) one constant; (2-6) five variables, each of

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[23] *Id*. at col. 9:15-18.

[24] *Id*. at col. 9:15-27.

[25] *Id*. at col. 9:27-29.

[26] *See id*. at col. 9:47-52.

which is multiplied by a separate constant; and (7-9) one variable used three times, in third-order polynomial form, and multiplied by a separate constant in each of its three appearances.[27]

The nine constants are empirically derived. Five of the six variables used are: (1) the difference between the second and final temperature readings of the first sensor, *i.e.*, the sensor that is closer to the "layer or sheet of material" covering the probe and in thermal contact with the skin;[28] (2-3) the rate of change, in degrees per second, of the first and second sensors after five intervals; and (4-5) the readings of the first and second sensors after the final interval.[29]

The sixth variable used in the formula is "$T_{avg}[,]$" which is defined by the '668 Patent as "the heat-flux derived temperature of [the '397 Patent]."[30] The '397 Patent claims "[a] high speed accurate temperature measuring device

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[27] *See id*. at col. 9:34-36 (providing the equation "Core Body Temperature = $(C_5 \times T_{b10\text{-}2}) + (C_{rdot5} \times T_{rdot5}) + (C_{bdot5} \times T_{bdot5}) + (C_{r10} \times T_{r10}) + (C_{b10} \times T_{b10}) + (C_3 \times T_{avg}) + (C_4 \times (T_{avg}))^2 + (C_7 \times (T_{avg}))^3 + C_6$)").

[28] *Markman* Op., 2011 WL 2693896, at *11 (construing the term "membrane").

[29] *See* '668 Patent at col. 9:52-61.

[30] *Id*. at col. 9:62-63. The '397 Patent was introduced into evidence as Exhibit 48. *See* Tr. (Yarden Direct) at 100:24-101:1 (identifying exhibit as the '397 Patent).

especially useful[] for measuring human body temperature[,]"[31] and teaches an algorithm "whereby the body temperature is calculated according to heat flux [*i.e.*, the rate of heat energy transfer] measured (a) between the body and a first temperature sensor and (b) between the first temperature sensor and a second temperature sensor (or sensors)."[32] In essence, the '397 algorithm is a method of rapidly predicting the thermoequilibrium temperature of the human body by taking temperature measurements at known intervals with two or more parallel sensors, separated by a known distance, with an insulating material of known thermal conductivity interposed between them, and with one sensor in thermal contact with the body (either directly or by being in thermal contact with a membrane that is in thermal contact with the body).[33]

The specification of the '668 Patent refers to variables (1-3) of the formula disclosed in the Appendix as "time dependent parameters of temperature change," and, unsurprisingly, refers to variables (4-5) as merely "temperature

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[31] '397 Patent at col. 5:46-47. The '397 Patent does not mention core body temperature or deep tissue temperature, and appears to have been intended for invasive use. *See id*. at col. 6:1-2 (Claim 1) (claiming "an elongated temperature probe with a rounded insertion tip for insertion into a body cavity").

[32] *Id*. at col. 1:46-49. *See* Tr. (Yarden Direct) at 84:3-6 ("[H]eat is [the] amount of energy. Heat *flux* [is the] amount of energy that [is] passing across a given area for a given period of time.") (emphasis added).

[33] *See* '397 Patent at col. 1:27-43; *id*. at col. 2:38-57.

measurements. . . ."[34] The sixth variable, *i.e.*, the output of the '397 algorithm, or T_{avg}, is identified by the '668 Patent as local body temperature.[35]

The '668 Patent further states that T_{avg} is calculated "using a function including the time-dependent parameters [of temperature change][;]"[36] another unsurprising statement, given that the inputs to the '397 algorithm (time-dependent temperature measurements taken by two sensors) correspond to the time-dependent parameters of temperature change used in the empirical formula disclosed in the Appendix.[37] (In my *Markman* order, I held that "'time-dependent parameters of temperature change' encompasses straight temperature difference [*e.g.* the reading of sensor one at interval ten minus the reading of sensor one at interval two] as

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[34] '668 Patent at col. 2:8-12 ("The thermometer is configured to perform the heat flux calculation so as to derive a value of the local temperature. The local temperature, together with the temperature measurements and the time dependent parameters of temperature change may then be used to calculate a core body temperature. The calculation is typically based on an empirically derived formula based on the aforementioned parameters.")

[35] *See id*. *See also id*. at col. 7:12-17 ("The formula [disclosed in the Appendix] is based on fitting a linear equation comprising several temperature-related parameters to clinically measured values of core body temperature. The temperature related parameters include sensor temperature readings, time-dependent temperature rates of change, and the value of local body temperature determined by the '397 algorithm.").

[36] *Id*. at col. 2:42-44.

[37] *See* '397 Patent at col. 4:64-67.

well as rates of temperature change.")[38]

ii. Prosecution History

During the prosecution history of the '668 Patent, the Examiner issued a final rejection holding Claims 1-13, 15, 19, 22-28, 33, and 36-38 as obvious over two references, "Fraden," which discloses calculating a deep tissue temperature at the forehead, and "Takashi," which discloses that the deep tissue temperature underestimates core temperature.[39] Yarden overcame this prior art by claiming that Fraden calculated deep tissue temperature, but taught away from correcting to core temperature by assuming that deep tissue temperature was a reliable approximation of core temperature.[40] Thus, the prosecution history record estops Medisim from denying that deep tissue temperature may be calculated by applying an infrared

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[38] *Markman* Op., 2011 WL 2693896, at *8.

[39] *See* '668 File History, 4/2/09 Final Rejection ¶ 2. Fraden, US Patent Application Publication 2005/0043631, discloses a thermometer that utilizes infrared technology. According to Yarden, Fraden "calculates deep tissue body temperature from time dependent parameters, but does disclose the additional step of correcting the deep body temperature to a core body temperature." *Id*. Takashi, an article from the Japanese Journal of Anaesthesiology, discloses a study showing that non-invasive forehead deep tissue thermometry, such as Fraden, underestimates the actual value of the core body temperature. *See id*.

[40] *See* '668 File History, 9/6/09 Response to Office Action at 10 ("Applicant respectfully disagrees and respectfully submits that it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Fraden's temperature probe to adjust or correct the deep tissue temperature calculated by the probe.").

thermometer to a patient's forehead.[41]

The Examiner also considered U.S. Application No. 60/572,651 (the "'651 Provisional"), a provisional patent application filed by Yarden prior to his application for the '668 Patent. The '651 Provisional is entitled "System for fast, non-invasive and accurate measurement of an object's temperature."[42] A fuller account of it is provided below.

2. Procedural History

After my *Markman* ruling, the parties made cross-motions under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[43] as well as Rules 702 and 403 of the Federal Rules of Evidence, to exclude the testimony of various experts. I ruled on these motions in an Opinion and Order dated March 6, 2012 (the "*Daubert*

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[41] *See Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1266 (Fed. Cir. 2012) ("A patentee's statements during reexamination can be considered during claim construction, in keeping with the doctrine of prosecution disclaimer."). The jury heard testimony supporting the same proposition. *See* Tr. (Direct Examination of David Lipson ("Lipson Direct") at 776:16-23 (discussing infrared technology) ("Q. If you take such a measurement at the temple, what temperature will you be calculating directly? A. If you are reading at this area which is right above, say, the temporal artery, you are reading what is now commonly referred to as the local deep tissue. It is the temperature under the skin in the tissue between, essentially, the artery and underneath the skin.").

[42] *See* '668 Patent at 2 (listing the '651 Provisional among the references considered by the Examiner).

[43] 509 U.S. 579 (1993).

Opinion" or "*Daubert* Op."), and on the motion for reconsideration subsequently brought by Medisim in an order dated April 23, 2012 (the "*Daubert* Reconsideration Op."). The parties then brought cross-motions for summary judgment. I decided these motions in an Opinion and Order dated November 28, 2012 (the "Summary Judgment Opinion" or "S.J. Op."). The relevant portions of these pre-trial rulings are summarized below.

a. The *Daubert* Opinion

The Summary Judgment Opinion provides the following summary of my rulings on the parties' *Daubert* motions:

> 1) Jack Goldberg—BestMed's expert on the validity of the '668 Patent—is qualified to opine in the area of digital, conductive thermometry. Goldberg may offer the following opinions: (1) that the specification of the '668 Patent does not enable the full scope of the claimed invention; (2) that Medisim's FHT-1 Digital Temple Thermometer . . . calculates core body temperature and therefore anticipated the '668 Patent; (3) that the FHT-1 calculates deep tissue temperature; and (4) that BestMed has not infringed Medisim's intellectual property. . . .
>
> 2) Dr. David Lipson—Medisim's expert on the validity of the '668 Patent—may opine that BestMed's KD-2201 thermometer meets the core body temperature limitation of the '668 Patent. Lipson may also testify that the KD-2201 thermometer meets the deep tissue temperature limitation of the '668 Patent, but only to the extent that he bases his opinion on the 510(k) letters and deposition testimony of K-Jump witnesses referenced in his

report.[44]

Lipson sought to testify that the accused device, BestMed's KD-2201 thermometer, met the deep tissue temperature limitation of the '668 Patent. In support of this conclusion, Lipson offered: (1) his own testing, which supposedly indicated that the KD-2201, a single-sensor conduction thermometer, measures deep tissue temperature when placed in 'test mode' (*i.e.*, a factory calibration mode where the actual temperature reading of the sensor is obtained, as opposed to a derived temperature), applied to the external skin, and allowed to reach thermoequilibrium; (2) the submissions that K-Jump, the manufacturer of the accused device, made to the FDA (the "510(k) Letters") describing the accused device; and (3) evidence drawn from the deposition of employees at K-Jump who were involved with designing the accused device (the "K-Jump Depositions").[45]

In the *Daubert* opinion, I found that the competent evidence of record showed that calculating a deep tissue temperature by measuring the thermoequilibrium temperature at the skin's surface was possible only through the zero-heat flux method, which requires at least two sensors and a heating element. I

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[44] S.J. Op., 2012 WL 5954757, at *3 (citing *Daubert* Reconsideration Op., No. 10 Civ. 2463, 2012 WL 1450420, at *2 (S.D.N.Y. Apr. 23, 2012); *Daubert* Op., 861 F. Supp. 2d 158, 167-74 (S.D.N.Y. 2012)).

[45] *See Daubert* Reconsideration Op., 2012 WL 1450420, at *2.

also found that utilizing the zero-heat flux method is an impossibility with the accused device, which lacks a heating element and has only one sensor.[46] On the basis of this finding, I entirely excluded, as an *ipse dixit*, Lipson's conclusion that the accused product meets the deep tissue temperature limitation of the '668 Patent.[47]

On reconsideration, despite having grave doubts about Lipson's ultimate conclusion that the accused product meets the deep tissue temperature limitation,[48] I amended my *Daubert* ruling to allow Lipson to testify to this conclusion, but only on the basis of the K-Jump Depositions and the 510(k)

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[46] *See Daubert* Op., 861 F. Supp. 2d at 175 & 175 n.121 (citing Michiaki Yamakage & Akiyoshi Namiki, *Deep Temperature Monitoring Using a Zero-Heat-Flow Method*, 17 J. Anesthesia 108, 111 (2003); Daniel I. Sessler, *Temperature Monitoring and Perioperative Thermoregulation*, 109 Anesthesiology 318, 319 (2008). Prior to trial, the parties stipulated that "[t]he scientific literature of record in this case shows that deep tissue temperature can be calculated from the skin's surface using zero-heat-flux." Stip. Facts ¶ 9.

[47] *See Daubert* Op., 861 F. Supp. 2d at 175-76 ("Lipson's determination that the KD-2201 measures deep tissue temperature at the skin surface is an unsupported *ipse dixit* conclusion. . . . Accordingly, Lipson may not testify that the KD-2201 meets the deep tissue temperature limitation of the '668 Patent.") (citations omitted).

[48] *See Daubert* Reconsideration Op., 2012 WL 1450420, at *2 (S.D.N.Y. 2012) ("I have serious doubts regarding whether Lipson's 'deep tissue temperature' opinions are correct.").

Letters.[49] Lipson remained barred from testifying on the basis of his "flawed empirical testing" of the accused device in test mode.[50] The rationale for my holding on reconsideration was that, although it was highly improbable that Lipson's testimony based on the K-Jump Depositions and the 510(k) Letters would ultimately be *sufficient* to prove that the accused product met the deep tissue temperature limitation, such testimony was nevertheless *admissible* under the standard established by *Daubert*.[51]

b. Medisim's Motion for Summary Judgment of No Inequitable Conduct

i. Decision

BestMed did not move for summary judgment on anticipation. However, Medisim raised a related issue by moving for summary judgment to dismiss BestMed's counterclaim for inequitable conduct. Inequitable conduct is a complete bar to enforcement of a patent, and may be proved by "clear and

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[49] *See id*.

[50] *Id*.

[51] *See id*. ("Because the Federal Rules of Evidence — and the case law in this Circuit — favor the admissibility of expert testimony and because courts should focus on an expert's methodology rather than his ultimate conclusions, . . . [I] conclude that Lipson may testify that the KD-2201 meets the '668 Patent. Accordingly, I now hold that he may give such testimony, insofar as it is based on the [K-Jump Depositions and the 510(k) Letters].").

convincing evidence [] show[ing] that the applicant made a *deliberate* decision to withhold a *known* material reference."[52]

One of the grounds alleged by BestMed in support of its counterclaim was that the FHT-1 anticipated the '668 Patent, and that Yarden therefore engaged in inequitable conduct when he failed to disclose Medisim's pre-critical date sales of the FHT line of thermometers to the PTO during the process of applying for the '668 Patent.[53] BestMed also argued that the '651 Provisional did not constitute prior art, because it was not published until after the critical date of the '668 Patent.[54]

In support of its motion for summary judgment on inequitable conduct, Medisim presented undisputed evidence that Yarden disclosed the '651 Provisional to the Examiner through an Information Disclosure Statement sent to the PTO on June 26, 2007, and that the Examiner checked a box indicating that he had reviewed it as prior art.[55] Medisim also asserted that during the prosecution of the '668 Patent, Yarden had a good faith belief that the '651 Provisional (which

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[52] *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1290 (Fed. Cir. 2011) (quotation marks and citations omitted) (emphasis in original).

[53] *See* S.J. Op., 2012 WL 5954757, at *18 (citations omitted).

[54] *See id*.

[55] *See id*. at *19 (citation omitted).

does not explicitly mention the FHT line of thermometers, or Medisim's commercial activities): (1) embodied the same technology as the FHT-1; and (2) did not meet the deep-tissue temperature limitation of the '668 Patent, and therefore was not anticipatory.[56] Based on these assertions, Medisim argued that Yarden had discharged his duty of disclosure to the PTO.[57]

On the strength of this argument, I granted summary judgment dismissing BestMed's inequitable conduct counterclaim. My reasoning was that, regardless of the merits of BestMed's underlying anticipation argument, there was insufficient evidence of Yarden's culpable state of mind to permit the issue to go to a jury.[58] As a consequence of prevailing on summary judgment, Medisim is judicially estopped from denying that: (1) the '651 Provisional is prior art, and therefore intrinsic evidence;[59] (2) the '651 Provisional describes the technology of the FHT-1 thermometer; and (3) Yarden applied for the '668 Patent on the basis of his belief that the FHT-1 did not meet the deep tissue limitation of the '668

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[56] *See id*. at *18-19.

[57] *See id*.

[58] *See id*.

[59] *See Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1372 (Fed. Cir. 2002) ("Prior art cited in the prosecution history falls within the category of intrinsic evidence.").

Patent.[60]

ii. The Anticipation Evidence Advanced by BestMed

In its unsuccessful opposition to Medisim's motion for summary judgment on inequitable conduct, BestMed offered the following evidence of anticipation (a ground upon which it did not bring a dispositive motion prior to trial): (1) Goldberg's opinions; (2) Yarden's deposition; (3) Medisim's marketing descriptions of its technology; and (4) the description of the invention in the '651 Provisional.[61] The former three pieces of evidence ultimately reached the jury in pertinent part. As for the '651 Provisional, although it was part of the intrinsic

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[60] *See, e.g., Intellivision v. Microsoft Corp.*, 484 Fed. App'x 616, 619 (2d Cir. 2012) (non-precedential) ("'[J]udicial estoppel[] generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase.'") (quoting *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (further quotation marks and citations omitted). This application of judicial estoppel is in accord with the testimony heard by the jury. *See* Tr. (Yarden Direct) at 106:9-15 ("We call it at that time FHT which is forehead thermometer, that was the previous model that we had, and . . . just to answer some issue that was raised yesterday saying that we didn't disclose the fact that we had this forehead thermometer in front of the [E]xaminer. Well, yes, we did, because if you look into this document which is now right on the ['668] [P]atent [*i.e.*, the '668 Patent's list of references, which mentions the '651 Provisional], we did disclose it indeed to the examiner."); *id*. (Medisim Summation) at 1647:4-10 ("It was clear, as Mr. Yarden testified, that the FHT-1 product was before the examiner who examined the '668 [P]atent, it was referenced in a provisional patent application, he testified about that. Another non-issue, another smokescreen set up to divert your attention.").

[61] *See* S.J. Op., 2012 WL 5954757, at *19.

evidence, it was not presented to the jury in *toto*; rather, it was presented to the jury by way of the parties' experts' reports.

Nevertheless, it is instructive — although unnecessary to resolving this motion — to consider the teachings of the '651 Provisional with respect to the deep tissue temperature limitation.[62] The '651 Provisional discloses a multi-sensor thermometer that measures time-dependent parameters of temperature change, and utilizes the '397 algorithm in order to calculate "inner body temperature[,]" which it refers to as "T_{deep}," from temperature measurements made at the skin's surface.[63] It also explicitly provides for correcting this "inner body temperature" to core temperature, stating that: "[t]he invention under discussion also makes use of the

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[62] I take judicial notice of the public record of the '651 Provisional under Fed. R. Evid. 201(b)(2). Notice is justified because the '651 Provisional is a public record filed with the PTO, and, moreover, one that the parties placed into the record, with a full and fair opportunity to be heard on it, during the summary judgment stage of the case. *See Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 2010-1500, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010) (non-precedential) (taking judicial notice of patent applications). *Cf. Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 514 n.3 (Fed. Cir. 1990) (taking judicial notice of first office action); *Iconfind, Inc. v. Google, Inc*., No. 11 Civ. 319, 2012 WL 158366, at *1 (E.D. Cal. Jan. 18, 2012) (taking judicial notice of patent's prosecution history).

[63] 5/20/04 '651 Provisional Specification, ¶ 1.9 ("Measuring of inner body temperature (hereafter T_{deep}) can be done on the exterior surface of the body."). *Cf.* 5/20/04 '651 Provisional Introduction at 5 ("The basic principal [sic] is to measure temperature and heat fl[u]x on the surface and based on that estimat[e] the value of deep tissue temperature.")

value of T_{deep} and the measured values of [the temperature on the skin's surface] and [heat flux measured on the skin's surface] as [an] input for empirically correcting the model by the additional term [change in heat flux] *in order to extract the core body temperature* from the local parameters."[64] Finally, it distinguishes between skin surface temperature and T_{deep} by stating that temperature measured at the skin's surface varies more with environment conditions than T_{deep}.[65]

In short, the '651 Provisional strongly suggests that the FHT-1 thermometer anticipates the '668 Patent. Indeed, on summary judgment, the only argument that Medisim could muster against the obvious inference that deep tissue temperature and T_{deep} are one and the same is that the '651 Provisional does not use the same *terms* as the '668 Patent, even though it describes the same process.[66] Had BestMed moved for summary judgment on anticipation, rather than defending

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[64] 5/20/04 '651 Provisional Summary of the Invention at 4.

[65] *Compare id*. ("However, the value of $T_{surface}$ [temperature at the skin's surface] is different from the value of T_{deep}. [Because] . . . the skin [is] exposed to the environment, $T_{surface}$ [] represent[s] also that effect and not only the value of T_{deep}.") *with* '668 Patent at col. 7:1-4 ("The local temperature determined by the '397 algorithm is less affected than the surface temperature at the measurement site is to external factors such as ambient temperature and humidity.").

[66] *See* Reply in Support of Medisim's Motion for Summary Judgment of No Inequitable Conduct ("Medisim IC Reply"), Doc. No. 116, at 5 n.2 ("The '651 Provisional . . . does not mention 'deep tissue' temperature as claimed in the '668 Patent, but rather refers only to 'T_{deep},' which expressly is defined in the '651 Provisional as an 'inner body temperature.'").

Medisim's motion for no inequitable conduct, it is likely that the motion would have been granted.[67]

The suspicion that BestMed could have ended this action earlier by seeking summary judgment on anticipation is strengthened by Yarden's deposition testimony. In a portion of his deposition that was subsequently displayed to the jury, Yarden testified that the FHT-1 "receives a value based on [an] algorithm that it is implementing the heat flow calculation [*i.e.*, the '397 algorithm] . . . it takes this temperature that was coming out of the algorithm of the heat flow and puts it into a third order polynomial which produces the [core] body temperature [*i.e.*, corrects to core]."[68]

The similarity between Yarden's description of the FHT-1 and the invention claimed by the '668 Patent is unmistakable. Moreover, in denying this similarity on summary judgment, Medisim offered only the conclusory testimony

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[67] *Cf.* S.J. Op., 2012 WL 5954757, at *19 ("Goldberg's opinion [on anticipation] may be relevant to whether Yarden was wrong, but it is irrelevant to whether Yarden believed the devices were covered by the '668 Patent and intentionally withheld information regarding their sales so as to deceive the PTO.") (citation omitted).

[68] *Id.* at *21 n.223 (quoting 2/2/11 Deposition of Moshe Yarden at 162:6-22). *Cf.* Tr. (Redirect Examination of Goldberg ("Goldberg Redirect")) at 1398:13-1399:18 (discussing the portion of Yarden's deposition just quoted and pointing out the similarity between Yarden's description of the FHT-1 and the '668 Patent).

of Yarden that the FHT-1 does not calculate deep tissue temperature, and the misleading and irrelevant argument that, at one point, the '668 Patent states that the '397 algorithm is only an exemplar of how deep tissue temperature may be calculated.[69] In sum, BestMed probably erred by failing to move for summary judgment on anticipation.

3. Trial Evidence

This section summarizes the relevant trial evidence not discussed above. *First*, it presents the testimony of Yarden and Lipson. *Second*, it presents the testimony of Goldberg, and *third*, it presents evidence relating to Medisim's pre-litigation descriptions of its technology, as well as evidence relating to the shift between the FHT-1 and the FHT-1A, which Medisim contends was the first thermometer to embody the '668 Patent.

a. Yarden's Testimony

i. The Innovation of the '668 Patent

At trial, Yarden testified that, prior to inventing the '668 Patent, he

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[69] *See* Medisim IC Reply at 4-5 (citing '668 Patent at col. 1:65-2:5). The argument is misleading because, as discussed above, the '668 Patent states at multiple points that deep tissue temperature is derived from the '397 algorithm, when that algorithm is implemented by devices like the FHT-1. It is irrelevant because meeting the deep tissue temperature limitation only requires that the FHT-1 "calculate . . . a deep tissue temperature," not that it exhaust the possible methods for calculating a deep tissue temperature.

had determined that Medisim's FHT-1 and FHT-2 thermometers required improvement, because they were inaccurate in extreme ambient temperatures (*e.g.*, a very hot room).[70] Yarden further testified that, some time after filing the '651 Provisional,[71] his research revealed that a temperature sensing patch attached to the surface of a patient's forehead would settle on a temperature that was much lower than either core temperature or oral temperature after approximately ten minutes.[72] He referred to this temperature as deep tissue temperature.[73]

Yarden further testified that the contemporaneous state of the art inaccurately treated deep tissue temperature as a reliable approximation of oral or core temperature, despite the fact that deep tissue temperature was "not . . . core or even close to it."[74] He then testified that his discovery that a user's deep tissue

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[70] *See* Tr. (Yarden Direct) at 101:16-24.

[71] *See id*. (Yarden Cross) at 264:10-14 ("Q. This aha moment occurred after you had filed the provisional specification that you thought about yesterday, is that right? A. That's right. If I recall, the provisional was way back 2002 or 2003, so that's right.").

[72] *See id*. (Yarden Direct) at 102:1-103:21.

[73] *Id*. at 103:22-104:3 ("[The temperature display of a temperature sensing patch applied to a patient's forehead for ten minutes] would be the local temperature, namely [] the temperature that will be prevailing under the skin, however this will not be the core or even close to it.").

[74] *Id*. at 104:3. *See id*. at 103:3-5 ("[T]he expectation was that [by leaving the temperature patches on patient's foreheads for ten minutes] we [would] get something which is very close to the patient temperature like the oral

temperature could be obtained by allowing a temperature sensing patch placed on the user's forehead to reach thermoequilibrium led him to improve upon the FHT line of thermometers with the '668 Patent, which first calculates a deep tissue temperature, and then corrects to core.[75]

ii. The Deep Tissue Temperature Limitation

Yarden testified that the portion of the formula disclosed in the Appendix incorporating T_{avg} calculates deep-tissue temperature, and that the balance of the formula corrects to core temperature.[76] Per Yarden's testimony, then, the embodiment of the '668 Patent disclosed in the Appendix calculates deep tissue temperature by solving the following equation: deep tissue = $(C_3 \times T_{avg}) + (C_4 \times T_{avg}^2) + (C_7 \times T_{avg}^3) + C_6$, where terms of the form C_X are constants.[77] This derived deep tissue temperature is then corrected to core temperature by the

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temperature.").

[75] *See id*. at 103:16-21 ("So, combining [my review of the prior art] with the patch results that we had, I came to the conclusion that having a thermometer that we'll be able to do a dual step[,] namely first calculate the local temperature and then correct it to the core temperature, it will be more accurate and will probably address our need for improvement of our previous models."). Notably, all of the features that Yarden described as essential to his innovation are present in the '651 Provisional.

[76] *See id*. at 110:1-12.

[77] *See* '668 Patent at col. 9:62-63.

balance of the equation disclosed in the Appendix. On the basis of this characterization of the Appendix, Yarden further testified that T_{avg} is not, itself, deep tissue temperature; for if it were, there would be no reason to perform the operations listed above in order to arrive at deep tissue temperature.[78]

iii. The FHT-1 Thermometer

On direct examination, Yarden testified that the FHT-1 employs "a fixed baseline . . . representing the lower end of the temperatures of the core body temperatures[,]" and that it "use[s] the output of the heat flux method [] to calculate the difference between that baseline and the" approximation of core temperature that the FHT-1 ultimately displays to the user.[79] Yarden likened this "fixed baseline" to a "reference line which represent[s] the lower end of the measurement range [of core temperature]. . . ."[80] Yarden testified that the "fixed baseline" employed by the FHT-1 could not be the same as a user's deep tissue temperature, because it has a constant value.[81]

On cross-examination, Yarden testified that the FHT-1 uses the heat-

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78 *See* Tr. (Yarden Direct) at 110:13-22.

79 *Id*. at 115:21-116:1.

80 *Id*. at 89:17-18.

81 *See id*. at 116:8-23.

flux algorithm disclosed in the '397 Patent in order to arrive at an intermediate temperature, and then performs the "further step" of "calculating [the] difference . . . above a base line" in order to arrive at the user's "core body temperature."[82] Yarden also testified on cross-examination that the '397 Patent discloses a general procedure by which the heat-flux method may be used in order to derive body temperature, but that additional steps were needed to "in order to derive [] local deep tissue [temperature]. . . ."[83] Soon after, Yarden acknowledged that the FHT-1 takes sensor readings, processes them using the '397 algorithm to arrive at an intermediate value, and then applies an algorithmic process in order to display an approximation of core temperature, but inexplicably insisted that this was not a "two step" process.[84] Yarden then testified that the limitations of the heat-flux

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[82] *Id*. (Yarden Cross) at 270:9-10; 271:4-7 ("The further step is taking that T_{avg} that we're getting out of the '397, and then calculating difference, which is around for a normal person around 2 to 3 degrees centigrade above a base line as we just show in the slide the other day.").

[83] *Id*. at 267:17-21.

[84] *See id*. at 273:11-274:1 ("Q. All right. So there is a second step after you obtain the initial value using the heat transfer algorithm of the '397 patent, correct? A. That's correct. Q. So will you agree with me that the FHT-1 device also uses a two step process to obtain the final result? A. Again, just to clarify. Q. No, yes or no, please? A. No. . . . In the sense that you mention. Q. Excuse me? A. Correction, two step, then the answer is no. Q. All right. But you do something to the value that you obtain or you change the number in some manner that you obtained after the FHT-1 has done the heat transfer algorithm calculation, correct? A. That's correct.").

algorithm disclosed in the '397 Patent are "explain[ed] clearly in the '668 [Patent's] appendix."[85]

On re-direct, Yarden identified the value of the fixed baseline as 95.7° Celsius.[86] Regarding this testimony, Medisim asserts that "Yarden misspoke and clearly meant Fahrenheit rather than Celsius."[87] Finally, Yarden testified that the invention embodied in the '397 Patent does not "measure deep tissue temperature."[88]

b. Lipson's Testimony

i. Deep Tissue Temperature

Like Yarden, Lipson testified that one of the advances of the '668 Patent is that it differentiated between core temperature and deep tissue temperature, whereas the prior art had equated the two.[89] Lipson further testified that this supposed false equivalence between core and deep tissue temperature

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[85] *Id*. at 267:21-22.

[86] *Id*. (Redirect Examination of Moshe Yarden ("Yarden Redirect")) at 324:3-6.

[87] Opp. Mem. at 4 n.6. Water boils at a temperature of 100°C under normal atmospheric conditions. A body temperature of 95.7°C would cause instant death.

[88] Tr. (Yarden Redirect) at 324:18-20.

[89] *See id*. (Yarden Direct) at 102:5-104:3; *id*. (Rebuttal Redirect Examination of Dr. David Lipson ("Lipson Rebuttal Redirect")) at 1554:2-6.

provides a non-invalidating explanation for certain of Medisim's pre-'668 Patent descriptions of its technology.[90]

On cross-examination, Lipson testified that 95°F is a "pretty reasonable estimate for a healthy person's [deep tissue temperature]. . . ."[91] He then testified that deep tissue temperature is lower than core temperature and higher than surface temperature, and, when measured at a healthy person's temple, will typically fall between 94°F and 98°F.[92]

ii. The FHT-1 Thermometer

Lipson testified that the FHT-1 "calculates some intermediate temperature and then displays an estimate of core body temperature[,]"[93] but does not calculate local deep tissue temperature.[94] Lipson further testified that he based this conclusion on his conversations with Yarden about the FHT-1's design, his

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[90] *See id*. at 1554:13-17. Lipson was not entirely consistent on this point: when asked whether a pre-litigation document of Medisim's referring to "deep tissues' temperature" could be referring to "pulmonary artery temperature," he replied "no way." *Id*. (Rebuttal Cross-Examination of Dr. David Lipson ("Lipson Rebuttal Cross")) at 1543:6-8.

[91] *Id*. (Cross-Examination of Dr. David Lipson ("Lipson Cross")) at 867:18-19.

[92] *See id*. at 869:18-870:7.

[93] Tr. (Lipson Rebuttal Redirect) at 1552:23-25.

[94] *Id*. at 1553:1-2.

own tests (in which he used the FHT-1 on himself), and "marketing information that suggested that[,]" with the FHT-1, Medisim was "directly trying to calculate core temperature at the temple site but not doing it in a manner described in the '668 patent."[95]

In his rebuttal testimony, Lipson describes his testing of the FHT-1 as follows:

> When I just tested [the FHT-1] on myself the software listing shows a particular equation that is the final one used for the prediction of temperature and I had the ability to ask Mr. Yarden about what that was. So, I simply did a couple of measurements on myself with the FHT-1 temperature and the key number that comes out of that equation was giving me a body temperature — or giving me a temperature number of around 92 degrees. But, in test mode, factory examination mode, it correctly read my forehead as being 95 degrees, my temple area. So, I knew that was just some intermediary result of the algorithm and the display temperature was giving me a reasonable reading from my body temperature. So, I was able to say between the test, the algorithm and making sure that I understood what the algorithm was by talking to Mr. Yarden, the FHT-1 does not calculate a local deep tissue and then correct it to core.[96]

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[95] *Id*. (Rebuttal Testimony of Dr. David Lipson) ("Lipson Rebuttal")) at 1522:15-18.

[96] *Id*. at 1521:14-1522:4. Lipson went on to testify that he had the FHT-1 for a "short period of time," and only tested it on himself. *See id*. at 1522:10-11. The jury heard abundant testimony that, when it is placed into 'test mode,' the FHT-1 thermometer displays the *actual* temperature reading of the sensors, as opposed to a derived value. *See, e.g., id*. (Yarden Cross) at 289:1-21 (testifying as to the procedure for placing the FHT line of thermometers into 'test mode,' and differentiating between "technical, lab accuracy, which will show you the actual

Shortly thereafter, and also during his rebuttal, Lipson testified, also on the basis of testing the FHT-1 thermometer on himself, that:

> There is an equation that actually is used at the final step of the operation of the [FHT-1] thermometer and that equation tells you how the display temperature is going to be calculated based on what is referred to as T-average[,] which is an intermediate result the thermometer calculates from making measurements from the temperature sensors. That equation was confirmed by Mr. Yarden, but when you actually put in an indicated temperature which you can measure and look at the local deep tissue temperature, you find out it can't make any sense.[97]

On cross-examination, Lipson testified that the sole distinction between the FHT-1 and the '668 is that the former does not calculate deep tissue temperature, and conceded that, if the FHT-1 calculated deep tissue temperature, it would anticipate the '668 Patent.[98] Moments earlier, in the context of obviousness,

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temperature sensed by the sensor[,]" and "clinical accuracy[,] where you would like to see how accurate . . . the device [will be] . . . [when] used in its normal mode").

[97] *Id*. (Lipson Rebuttal) at 1524:6-15. Yarden also repeatedly testified that the intermediate temperature of the FHT-1 is the output of the '397 algorithm, and that the value derived from the '397 algorithm is then used in an algorithm that estimates core temperature. *See* Tr. (Yarden Redirect) at 324:5-9; *id*. (Yarden Cross) at 271:4-7; *id*. at 272:8-10. Lipson made no mention of the "fixed baseline" referenced by Yarden.

[98] *See id*. (Lipson Rebuttal Cross) at 1539:17-22 ("Q. So the difference — we're talking about deep tissue temperature. If the intermediate temperature calculated by the FHT-1 thermometer, this the prior art FHT-1 thermometer, is a deep tissue temperature, then does it anticipate the claims of the '668 patent? A. It would certainly anticipate claim one.").

Lipson had engaged in the following colloquy with the Court:

> THE WITNESS: [O]nce I understand [] what the temperature I'm looking at is, and I know I'm in an environment where it's cooling, I just put a little insulation around the transducer, the thermistor, and I can [take] [an] external surface measurement, and I know it's going to look at the tissue underneath the skin.
>
> THE COURT: So you're saying you can take an invasive thermometer and put it on your temple, put some insulation on, and thereby replicate this process of getting . . . the deep tissue [temperature]?
>
> THE WITNESS: *That's essentially what the FHT-1 did*. Yes, I could do that.[99]

c. Goldberg's Testimony

Goldberg testified at trial that the FHT-1 met all the claim limitations of the '668 Patent.[100] Regarding the deep tissue temperature limitation, Goldberg testified — while a portion of the FHT-1's source code was on display — that:

> The routine [*i.e.*, the portion of the source code allegedly responsible for calculating deep tissue temperature] takes these temperature change parameters and processes them in a manner consistent with arriving at a deep tissue temperature. It is important to note that we know from other documents that the FHT-1 is utilizing methodology that's described in the '397 patent, that it uses two sensors, that it uses the heat flux algorithm, and because of that the calculation that's here is consistent with

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[99] *Id*. at 1536:5-17 (emphasis added).

[100] *See id*. (Direct Examination of Jack Goldberg ("Goldberg Direct")) at 1189:11-14.

the calculation of a deep tissue temperature.[101]

In short, Goldberg identified for the jury a portion of the source-code of the FHT-1 that is consistent with the '668's teachings for arriving at a deep tissue temperature, *i.e.*, practicing the '397 algorithm.[102] Medisim's cross-examination of Goldberg on the deep tissue limitation was confined to attempting to show that Goldberg was merely parroting the report of Gilliland, BestMed's consulting expert. That line of questioning did not bear fruit.[103]

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[101] *Id*. at 1188:13-20 (citing Defendant's Trial Exhibit ("DX")-ON, source-code from the FHT-1, at MED016839).

[102] *See id*. at 1188:13-20. *See also id*. at 1197:15-24 (Goldberg testimony that the FHT-1 "estimat[es] the deep tissue temperature by solving a time-dependent heat conduction transfer equation" on the basis that "it utilizes the heat conduction methodology of R.A.T.E. [Medisim's trademarked description of its technology], and . . . the software shows the step."); *id*. at 1199:12-14 ("I can see the function that calculates the deep tissue temperature and utilizes the said time-dependent parameters right there in the software."). Goldberg also identified a portion of the FHT-1's source code that implements a third-order polynomial, of the sort found in the Appendix, and, on this basis, testified that the FHT-1 practiced the correcting to core limitation of the '668 Patent. *See id*. at 1198:10-15 ("Again, you know, the software [of the FHT-1] shows this polynomial function. The sub-routine is actually named P-o-l-i-n-o-m, Polinom, and we know that it calculates a deep tissue temperature, and we know that it corrects to core. So this limitation is also practiced through the use of the device.").

[103] *See id*. (Goldberg Cross) at 1317:3-1326:25. Medisim's unsuccessful attempt to depict Goldberg as a mere conduit for Gilliland echoed its unsuccessful motion to strike the portions of Goldberg's report analyzing the FHT-1 under *Daubert*. *See Daubert* Op., 861 F. Supp. 2d at 169 (concluding that Goldberg was entitled to reference Gilliland's report, because Goldberg conducted an independent investigation).

d. Medisim's Pre-Litigation Descriptions of Its Technology

Medisim gave its heat-conduction thermometer technology the commercial name R.A.T.E., which stands for "Rapid Accurate Temperature Establishment."[104] One of the bases for BestMed's anticipation argument is that, prior to this action, Medisim described its R.A.T.E. technology in terms strikingly similar to the operation of the '668 Patent.

For example, Yarden sent an e-mail to K-Jump and BestMed on May 9, 2003 for the purposes of explaining Medisim's technology.[105] This e-mail contains an attachment, titled Products Outline, that discloses that R.A.T.E. technology employs a heat-flux algorithm identical to that taught by the '397 Patent.[106] This attachment also states that "in R.A.T.E™ [technology] extrapolation is not performed. In other words, a future value is not predicted but a calculation made, in real time, of the temperature existing under the skin."[107] The

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[104] Tr. (Yarden Direct) at 86:1-4.

[105] *See* DX-TK, 5/9/03 e-mail from Yarden to BestMed and K-Jump Officials, at K-J 01780 ("Attached please find some info regarding our company and technology for tomorrow['s] video-con.").

[106] *Compare id*. at K-J 01798-01799 *with* '397 Patent at col. 2:50-57.

[107] DX-TK at K-J 01803. The deep tissue temperature limitation of the '668 Patent states: "to calculate, a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature

Products Outline also contains a diagram depicting a cross section of tissue layers, running from "blood vessels," to "deep tissues," to "subcutaneous fat," to the "skin surface," and a probe pressed against the skin surface.[108] On direct examination, Stanley Cohen, BestMed's CEO, testified that he received no indication from Medisim that the technology described in the Products Outline was not incorporated into the FHT-1 thermometer, which BestMed began selling on behalf of Medisim shortly thereafter.[109]

Similarly, Goldberg testified that, in addition to the Products Outline attached to the May 9 e-mail, one of the documents that he relied upon in forming his conclusion of anticipation was another Products Outline released by Medisim prior to the critical date of the '668 Patent.[110] This document states that "[b]y utilizing the conductive R.A.T.E™ technology, FHT™ thermometers measure deep tissues' temperature and thus the effect of the environmental conditions is

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sensors. . . ." '668 Patent at col. 10:13-15.

[108] DX-TK at K-J 01789.

[109] *See* Tr. (Direct Examination of Stanley Cohen ("Cohen Direct") at 659:25-660:5 ("Q. Did Medisim ever advise you that [the R.A.T.E.] technology [explained in DX-TK] was not going to be used in the FHT-1 thermometer? A. No. Q. Did they ever advise you that this technology was not found in their FHT-1 thermometer? A. No.").

[110] *See id*. (Goldberg Direct) at 1188:21-1189:12.

minimized."[111] Yarden conceded that this document referred to the FHT-1,[112] but testified that its reference to "deep tissue*s'* temperature," as opposed to "deep tissue temperature," was merely meant to differentiate R.A.T.E. technology from infrared technology.[113]

e. The Shift from the FHT-1 to the FHT-1A

Yarden testified that the first Medisim product to incorporate the technology of the '668 Patent was the FHT-1A thermometer, which was first sold in mid-2007.[114] Yarden also testified that "there were phone calls, discussions, and there . . . was an e-mail where" BestMed and Medisim contemporaneously discussed the new technology allegedly embodied in the FHT-1A.[115]

On cross-examination, Yarden conceded that he had not personally informed BestMed of the switch from the FHT-1 to the FHT-1A, but believed that someone at Medisim had.[116] Yarden also testified that the FHT-1A looked the

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[111] DX-IF (Medisim Ltd. Products Outline, marketing literature prepared by Medisim some time between 2003 and 2006).

[112] *See* Tr. (Yarden Cross) at 303:15-20.

[113] *See id*. at 304:7-16.

[114] *See id*. (Yarden Direct) at 117:6-118:6.

[115] *Id*. at 176:11-14.

[116] *Compare id*. (Yarden Cross) at 303:11-15 (" Q. [W]hen the FHT-1 was replaced by the FHT-1A as you testified, yesterday you said that you did in

same as the FHT-1, but contained different internals, *i.e.*, it ran different source code and had a different circuit board.[117]

Beyond Yarden's testimony, no evidence of record supports the conclusion that the FHT-1A was significantly different from the FHT-1. No analysis comparing the FHT-1A's source code or internal architecture with the FHT-1 was presented to the jury. Nor did consumers appear to appreciate the difference between the products: the evidence of record shows that BestMed enjoyed the same sales with the FHT-1A as it had with the FHT-1.[118]

Furthermore, the uncontradicted evidence is that Medisim did not

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fact notify BestMed about that change. Do you recall that? A. Yes, but not me personally necessarily. I mean Medisim informed."), *with id*. (Yarden Direct) at 176:5-18 ("THE COURT: So, Mr. Yarden, if you would listen to this question: Prior to mid-2007, had you been in communication with the representatives of BestMed about your development of the technology behind the FHT-1A product? THE WITNESS: The answer is yes. . . . Q. Did you inform BestMed in advance before you started shipping them the FHT-1A thermometer rather than the FHT-1 thermometer? A. Yes.").

[117] *See id*. (Yarden Cross) at 294:7-14.

[118] *See id*. (Direct Examination of Robert McSorley, BestMed's expert on damages) at 1419:14-19 ("[A]fter this alleged transition from the FHT-1 to the FHT-1A, sales of BestMed [products] did not increase. There is a six quarter period which is a year and a half during which these alleged switch — the alleged FHT-1A was on the market where the sales were pretty much consistent from where they were in 2005, 2006 and 2007.").

suggest to BestMed that it mark the FHT-1A as "patent pending."[119] In fact, the only contemporaneous evidence of record showing that Medisim informed BestMed of the shift from the FHT-1 to the FHT-1A was an e-mail sent by a Medisim employee to Stanley Cohen, which references the FHT-1A in its subject line, but provides no indication that it embodies a new technology.[120]

C. Unjust Enrichment

1. The Parties' Contracts

Like many rivals, Medisim and BestMed were once allies. From November 2004 to May 2007, BestMed marketed and sold Medisim's digital, conductive forehead thermometers in the United States under the International Distributorship Agreement (the "IDA") entered into between the parties.[121] While the IDA was in effect, BestMed was privy to technical information concerning Medisim's thermometers, and received a draft of the thermometers' IFU.[122] By

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[119] *Id*. (Redirect Examination of Stanley Cohen) at 758:10-15.

[120] *See id*. (Cohen Direct) at 656:3-658:6 (discussing DX-PN — e-mail from Medisim employee to Cohen asking to switch the warehousing lot number of Medisim's thermometers — and testifying that he had no recollection of being informed that the FHT-1A embodied new technology).

[121] *See* 11/24/04 IDA, DX-TU.

[122] *See id*.

mid-2005, Medisim was supplying BestMed with its FHT-1 thermometer.[123]

As a result of a disagreement about the renewal of the IDA, the parties entered into a Purchase and Sale Agreement ("PSA"),[124] which commenced on May 1, 2008 and terminated on May 1, 2009.[125] Among other things, the PSA permitted the parties to sell competing products to customers as of May 1, 2008, so long as deliveries were not made prior to May 1, 2009.[126] Moreover, through the PSA, the parties waived any claims "arising from the actual or alleged performance, termination, breach or continuation of [the IDA] and the parties' subsequent correspondence relating to [the IDA] and the proposed renewal or replacement thereof."[127]

2. Procedural History

On summary judgment, BestMed moved to dismiss Medisim's unjust enrichment claim on the related grounds that: (1) it was just a catch-all for Medisim's other claims; and (2) that it was preempted. The motion was denied, on the basis that the Lanham Act does not preempt a state law claim of unjust

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123 *See* Tr. (Yarden Direct) at 90:15-19.

124 *See id*. at 198:1-201:20.

125 *See* PSA, DX-PM, at 00094.

126 *See id*.

127 *Id*. at 00095.

enrichment.[128]

3. Trial

Like the invalidity inquiry, the unjust enrichment inquiry was significantly narrowed prior to its submission to the jury. Medisim's claim for unjust enrichment was vaguely pleaded, and fell in the interstices of its claims for patent infringement, copyright infringement, unfair competition (state and federal), false advertising (state and federal), and Deceptive Acts and Practices.[129] Of these claims, federal unfair competition, false advertising, and Deceptive Acts and Practices were dismissed on summary judgment.[130] Moreover, Medisim's claim for copyright damages was dismissed prior to the case's submission to the jury.[131]

Ultimately the jury was charged with deciding whether "BestMed has been unjustly enriched by obtaining profits from the sale of its thermometers[,]" and in determining damages for unjust enrichment, was instructed to consider "the value of the profits that BestMed made from its sale of thermometers."[132] The jury

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[128] *See* S.J. Op., 2012 WL 5954757, at *14 ("[E]ven if Medisim's unjust enrichment claim duplicates its Lanham act claims . . . dismissal of [the] unjust enrichment claim is not warranted.").

[129] *See* Complaint, Doc. No. 1, ¶¶ 65-69.

[130] *See* S.J. Op., 2012 WL 5954757, at *1.

[131] *See* Tr. (JMOL Conference) at 1221:1-1223:1.

[132] *Id*. (Jury Instructions) at 1726:9:1727:2.

found against Medisim on its state unfair competition claim, which Medisim concedes "overlap[s] significantly" with its claim for unjust enrichment.[133]

III. LEGAL STANDARD

A. Judgment as a Matter of Law

In a case arising under the patent laws, the rules of the regional circuit governs the standard of review applicable to a JMOL motion.[134] In the Second Circuit, a Federal Rule of Civil Procedure ("Rule") 50(b) motion for JMOL may be granted only if "a reasonable jury would not have a legally sufficient evidentiary basis to find for the [non-movant] on that issue."[135]

"[A] district court can grant the motion only if after viewing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in favor of the non-moving party, it finds that there is

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[133] *Id*. (Charging Conference) at 1505:13-16 ("For its next motion Medisim asserts, as a matter of law, that it has prevailed on its New York unjust enrichment claim. The facts and circumstances overlap significantly with the unfair competition claim.").

[134] *See Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 18 (Fed. Cir. 2012).

[135] *Cameron v. City of New York*, 598 F.3d 50, 59 (2d Cir. 2010) (alteration in original) (quoting Fed. R. Civ. P. 50(a)(1)).

insufficient evidence to support the verdict."[136] Thus, JMOL is appropriate where "there exists such a complete absence of evidence supporting the verdict that the jury's findings could only have been the result of sheer surmise and conjecture, or the evidence in favor of the movant is so overwhelming that reasonable and fair minded [persons] could not arrive at a verdict against [it]."[137] "If the court grants a renewed motion for judgment as a matter of law, it must also conditionally rule on any motion for a new trial by determining whether a new trial should be granted if the judgment is later vacated or reversed."[138]

A motion under Rule 50(b) is properly made only if the movant "sought relief on similar grounds under Rule 50(a) before the case was submitted to the jury."[139] "'Generally a party is not entitled to [JMOL under Rule 50(b)] on any ground that [it] has not raised in a motion for a [JMOL under Rule 50(a)] . . .

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[136] *Fabri v. United Techs. Int'l, Inc.*, 387 F.3d 109, 119 (2d Cir. 2004) (citing *Tolbert v. Queens Coll.*, 242 F.3d 58, 70 (2d Cir. 2001)).

[137] *Tepperwien v. Entergy Nuclear Operations, Inc.*, 663 F.3d 556, 567 (2d Cir. 2011) (quotations marks and citations omitted, alterations in original).

[138] Rule 50(c)(1).

[139] *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486 n.5 (2008). *Accord Bracey v. Board of Educ. of City of Bridgeport*, 368 F.3d 108, 117 (2d Cir. 2004) ("A post-trial Rule 50(b) motion for judgment as a matter of law is properly made only if a Rule 50(a) motion for judgment as a matter of law has been made before submission of the case to the jury.") (collecting cases).

and the [Rule 50(a)] motion must have state[d] the specific grounds therefor.'"[140] In order to properly preserve a Rule 50(b) motion, "[t]he [pre-verdict] JMOL motion must at least identify the specific element that the defendant contends is insufficiently supported. . . . A generalized challenge is inadequate."[141]

B. New Trial

"Unlike a motion for judgment as a matter of law, a motion for a new trial may be granted even if there is substantial evidence to support the jury's verdict."[142] Nevertheless, "'[a] motion for a new trial ordinarily should not be granted unless the trial court is convinced that the jury has reached a seriously erroneous result or that the verdict is a miscarriage of justice.'"[143] A court may set aside the verdict and order a new trial even if no motion for JMOL was made under

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[140] *Northrop v. Hoffman of Simsbury, Inc.*, 12 Fed. App'x 44, 49 (2d Cir. 2001) (quoting *Smith v. Lightning Bolt Prods., Inc.*, 861 F.2d 363, 367 (2d Cir. 1988) (further citations omitted)).

[141] *Gierlinger v. Gleason*, 160 F.3d 858, 869 (2d Cir. 1998) (quotation marks and citations omitted).

[142] *Caruolo v. John Crane, Inc.*, 226 F.3d 46, 54 (2d Cir. 2000) (quotation marks and citation omitted).

[143] *Townsend v. Benjamin Enters., Inc.*, 679 F.3d 41, 51 (2d Cir. 2012) (quoting *Medforms, Inc. v. Healthcare Mgmt. Solutions, Inc.*, 290 F.3d 98, 106 (2d Cir. 2002)).

Rule 50(a).[144]

C. Patent Invalidity

1. Burden of Proof

Section 282(a) of Title 35 of the United States Code states that:

> A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.[145]

Invalidity defenses to patent infringement require proof by clear and convincing evidence.[146] Under the *Barbed-Wire*[147] doctrine,

> [C]orroboration is required of any witness whose testimony alone is asserted to invalidate a patent. Both physical evidence and oral testimony of a disinterested party can serve to satisfy the corroboration requirement. The sufficiency of the corroborating evidence is assessed according to the following factors: (1) the relationship between the

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[144] *See Bracey*, 368 F.3d at 117 (granting Rule 59 motion in the absence of Rule 50(a) motion). *Cf. Macquesten Gen. Contracting, Inc. v. HCE, Inc.*, 128 Fed. App'x 782, 784 (2d Cir. 2005) ("While MacQuesten failed during the trial to make a motion for judgment as a matter law pursuant to Rule 50(a), that is no impediment to a Rule 59(a) motion.").

[145] 35 U.S.C. § 282(a).

[146] *See Microsoft Corp. v. i4i Ltd. P'ship*, — U.S. — , 131 S.Ct. 2238, 2242 (2011).

[147] *The Barbed Wire Patent*, 143 U.S. 275, 284 (1892).

> corroborating witness and the alleged prior user, (2) the time period between the event and trial, (3) the interest of the corroborating witness in the subject matter in suit, (4) contradiction or impeachment of the witness' testimony, (5) the extent and details of the corroborating testimony, (6) the witness' familiarity with the subject matter of the patented invention and the prior use, (7) probability that a prior use could occur considering the state of the art at the time, (8) impact of the invention on the industry, and [(9)] the commercial value of its practice.[148]

2. Anticipation

Novelty is a requirement of patentability. A patent may not validly issue if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention[,]" or if the claimed invention was described in an earlier-filed patent or application by a different inventor.[149]

A patent claim that is not novel is said to be anticipated. "[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference."[150] "Anticipation is a question of fact reviewed for

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[148] *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1159-60 (Fed. Cir. 2004) (quotation marks and citations omitted) (alterations in original).

[149] 35 U.S.C. § 102(a).

[150] *Celeritas Techs., Ltd. v. Rockwell Intern. Corp.*, 150 F.3d 1354, 1361 (Fed Cir. 1998) (citing *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 715 (Fed. Cir. 1984)).

substantial evidence when tried to a jury."[151]

> Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses [sic] interpretation of the claim element, and explain in detail how each claim element is disclosed in the prior art reference. The testimony is insufficient if it is merely conclusory. And if the testimony relates to prior invention and is from an interested party . . . it must be corroborated.[152]

D. Unjust Enrichment Under New York Law

Under New York law, a plaintiff seeking relief under a theory of unjust enrichment must show "(1) that the defendant benefitted; (2) at the plaintiff's expense; and (3) that equity and good conscience require restitution."[153]

> The theory of unjust enrichment lies as a quasi-contract claim. It is an obligation the law creates in the absence of any agreement. The existence of a valid and enforceable written contract governing a particular subject matter ordinarily precludes recovery in quasi-contract for events arising out of the same subject matter.[154]

An unjust enrichment claim may not impinge upon an area governed by the federal

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[151] *Whitserve, LLC*, 694 F.3d at 2 (citing *Orion IP, LLC v. Hyundai Motor Am.*, 605 F.3d 967, 974 (Fed. Cir. 2010)).

[152] *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002) (citations omitted).

[153] *Leibowitz v. Cornell Univ.*, 584 F.3d 487, 509 (2d Cir. 2009).

[154] *Diesel Props S.r.l. v. Greystone Bus. Credit II LLC*, 631 F.3d 42, 54 (2d Cir. 2011) (quotation marks and citations omitted).

patent law. Thus, "[i]n the absence of an incremental benefit conferred, any attempt to obtain a patent-like royalty for the making, using, or selling of a product in the public domain under the rubric of state unjust enrichment law is preempted."[155]

IV. DISCUSSION

A. The '668 Patent Is Anticipated by the FHT-1 Thermometer

The overwhelming strength of BestMed's anticipation argument should be apparent from the detailed recitation of facts provided above. The only issue in contention is whether the FHT-1 meets the deep tissue temperature limitation of the '668 Patent, and, as discussed above, BestMed had probably created a record sufficient to resolve this issue in its favor on summary judgment. With the addition of the evidence adduced at trial, the conclusion of anticipation is inescapable.

In support of its motion for JMOL on anticipation, BestMed points to: (1) the intrinsic evidence; (2) the testimony of Goldberg showing that the source code of the FHT-1 embodies the deep tissue temperature limitation of the FHT-1; (3) the copious pre-litigation documents authored by Medisim stating that its R.A.T.E. technology measures the temperature prevailing under the skin; (4) the

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[155] *Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1382 (Fed. Cir. 2005).

absence of evidence marking the shift between the FHT-1 and the supposedly revolutionary FHT-1A; and (5) the contradictory testimony offered by Medisim.[156]

In its opposition, Medisim takes pains to avoid addressing the substance of BestMed's contentions. Medisim begins by arguing that BestMed failed to preserve its right to bring a post-trial motion for JMOL on invalidity by first bringing a motion for JMOL prior to the cases's submission to the jury.[157] I have already ruled that this argument has no merit, and I do so here again, for the same reasons I stated previously.[158]

Medisim's second attempt to avoid confronting the anticipation evidence presented to the jury involves mischaracterizing BestMed's argument for JMOL. Medisim asserts that "BestMed seeks JMOL on anticipation solely on the grounds that the *fixed baseline* of the FHT-1 device is the same as the 'deep tissue

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[156] *See* Def. Mem. at 2-7.

[157] *See* Opp. Mem. at 2 ("BestMed failed to previously move for JMOL on invalidity . . . despite multiple opportunities to do so.").

[158] *See* 3/18/13 Order, Doc. No. 190. BestMed's motion for a new trial is granted, conditioned on an appellate court determining that it failed to preserve its right to bring a post-trial motion for JMOL. In this event, I will then entertain a motion for summary judgment on anticipation prior to the commencement of a new trial. *Cf. ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1326 (Fed. Cir. 2012) ("In remanding for a limited new trial [on literal infringement and obviousness] . . . we do not foreclose the district court from entertaining a motion for summary judgment on these issues that might obviate the need for a further trial.")).

temperature' claimed in the '668 [P]atent. . . ."[159] Of course, this is not BestMed's argument: in fact, BestMed argues that the *intermediate temperature* of the FHT-1 reads on to the 'deep tissue temperature' limitation of the '668 Patent,[160] not that the 'fixed baseline' reads on to the limitation.

The keystone of this argument is the intrinsic evidence. As discussed at length above, the '668 Patent makes it abundantly clear that deep tissue temperature may be derived from the '397 algorithm. Further, there is no dispute that the non-invasive FHT-1 thermometer utilized the '397 algorithm in order to arrive at an intermediate temperature. In fact, Yarden conceded at trial that the FHT-1 thermometer was marked with the '397 Patent.[161] Given these facts, Goldberg's uncontradicted testimony that source code of the FHT-1 thermometer implements the '397 algorithm to arrive at an intermediate temperature constitutes strong evidence of anticipation, particularly when coupled with Yarden's deposition testimony admitting that the FHT-1 uses the '397 algorithm to arrive at an intermediate temperature, and then corrects to core via a third-order

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[159] Opp. Mem. at 3 (emphasis added) (citing Def. Mem. at 2, which makes no mention of the 'fixed baseline').

[160] *See* Def. Mem. at 3 (arguing that "the overwhelming weight of the evidence demonstrates that the *intermediate body temperature* calculated by the prior art FHT-1 was a deep tissue temperature.").

[161] *See* Tr. (Yarden Cross) at 271:19-22.

polynomial.[162]

Medisim's pre-litigation descriptions of its R.A.T.E. technology corroborate Goldberg's anticipation conclusion. As I must, I fully credit the jury's implicit finding that Yarden's self-interested testimony distinguishing "deep tissue temperature" from "deep tissues' temperature" was convincing. I also fully credit the jury's implicit finding that some of Medisim's contemporaneous marketing documents mistook deep tissue temperature for core temperature, or vice versa.

Nevertheless, the uncontroverted fact is that, in the process of pitching its thermometers to BestMed, Medisim represented that its R.A.T.E. technology calculated "the temperature existing under the skin[,]"[163] a phrase that the parties agree corresponds to deep tissue temperature.[164] Indeed, as BestMed points out,[165] Medisim's pre-litigation characterization of R.A.T.E. technology reads on to the

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[162] *See id*. (Goldberg Redirect) at 1398:13-1399:18 (discussing Yarden's deposition testimony while it was displayed to the jury).

[163] DX-TK at K-J 01803.

[164] Medisim cavils that "BestMed['s] sole attempt[] to link DTX-TK to the FHT-1 device is based upon Mr. Cohen's testimony that Medisim did not advise Mr. Cohen that the technology of DTX-TK is 'not going to be used' or 'was not found' in the forthcoming FHT-1 device." Opp. Mem. at 5 n.7. Given that DTX-TK is a marketing document used by Medisim in the process of pitching the FHT-1 to BestMed, and the fact that BestMed began selling the FHT-1 shortly thereafter, this argument is not convincing. More to the point, it is not evidence.

[165] *See* Reply Mem. at 3.

deep tissue limitation of the '668 Patent almost word-for-word.[166] In short, because the underlying physical process described by Medisim's marketing documents corresponds to the deep tissue temperature limitation, a reasonable jury would necessarily find these documents corroborative of anticipation.

Finally, the absence of contemporaneous evidence marking the switch from the FHT-1 to the FHT-1A, as well as the absence of evidence that the source code of the FHT-1A differed from that of the FHT-1, provide additional support for finding anticipation. The only evidence offered by Medisim that it notified BestMed of the switch to the FHT-1A consists of one cryptic e-mail, which does not reference any new technology, and Yarden's unsupported assertion that somebody at Medisim kept BestMed apprised of the innovation of the FHT-1A.

Of course, "'conclusory assertions . . . do 'not show the existence of a genuine issue of fact to be tried.'"[167] Moreover, even if Yarden's unsupported assertion that some unnamed person at Medisim informed BestMed of the new

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[166] *Compare* DX-TK at K-J 01803 ("a calculation [is] performed of the temperature existing in the blood vessels under the skin at that moment, which causes the measured flow") *with* '668 Patent at col. 13:15 ("to calculate[] a deep tissue temperature of the body at a location under the skin that is a source of heat conducted to the one or more temperature sensors").

[167] *Morales v. Rooney*, Nos. 10 Civ. 1692, 10 Civ. 1702, 2013 WL 322784, at *1 (2d Cir. Jan. 29, 2013) (quoting *Major League Baseball Props., Inc. v. Salvino*, Inc., 542 F.3d 290, 310 (2d Cir. 2008)).

technology supposedly embodied in the FHT-1A is credited, the complete absence of evidence relating to the FHT-1A's internal operations and its impact on BestMed's sales, as well as the uncontradicted evidence that Medisim did not ask BestMed to mark the FHT-1A patent-pending, corroborate a finding of anticipation.

The evidence presented by Medisim does nothing to disturb the conclusion that a reasonable jury would necessarily have found anticipation. Because Medisim's principal strategy lay in mischaracterizing BestMed's argument, its argument in opposition to BestMed's *actual* argument is relegated to a footnote.[168] In this footnote, Medisim advances the conclusory testimony of Yarden and Lipson, upon which no reasonable juror could have relied.[169]

One problem common to both Lipson and Yarden's testimony is that, while both offer conclusory denials that the intermediate temperature of the FHT-1 is a deep tissue temperature, neither provides a convincing account of what the intermediate temperature actually *is*. Lipson's conclusion on this limitation

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[168] *See* Opp. Mem. at 4 n.5 ("Both Mr. Yarden and Dr. Lipson further testified that the output of the heat flux algorithm of the '397 patent practiced by the FHT-1 device (T_{avg}) does not calculate deep tissue temperature.") (citing (Tr. (Yarden Cross) at 267:12-22; *id*. (Goldberg Rebuttal) at1524:6-19)).

[169] *See Whitserve, LLC*, 694 F.3d at 23 (reversing denial of JMOL of anticipation where patentee's expert merely offered conclusory testimony).

appears to be entirely based on placing the FHT-1 in test-mode, applying it to his temple, and comparing its display temperature at equilibrium to the "number that comes out of [the] equation," provided to him by Yarden, "that is the final one used [by the FHT-1] for the prediction of temperature. . . ."[170] Because the "number that comes out of the equation" was 92°F, and the measured temperature of his forehead when the FHT-1 was used in test-mode was 95°F, Lipson concluded that the FHT-1 does not measure a deep tissue temperature.[171]

Even if the jury managed to follow Lipson's theory, this testimony provides no basis for a finding of no anticipation. Lipson's account of his test did not mention its reliability, accuracy, acceptance in the field, or, generally, make any attempt to persuade a reasonable juror that it was a method capable of determining whether a device calculated deep tissue temperature. Based on Medisim's description of Lipson's test in its opposition to the present motion,[172] what Lipson had in mind was apparently that the thermo-equilibrium of his temple when measured using the FHT-1 in test mode was his deep tissue temperature, which differed from the undisclosed algorithm for calculating an intermediate

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170 Tr. (Lipson Rebuttal) at 1521:14-1522:4.

171 *Id*.

172 *See* Opp. Mem. at 5-6

temperature that he allegedly received from Yarden.

Notably, this is the *exact* test that I excluded Lipson from relying on in my *Daubert* ruling, on the basis that the thermo-eqilibrium temperature at the skin's surface is not equivalent to deep tissue temperature. For the same reason, his self-test cannot support the jury's verdict of no anticipation.[173] Moreover, even ignoring Lipson's flawed assumption that the FHT-1 used in test-mode could measure deep-tissue temperature, his conclusory account of the undisclosed algorithm provided to him by Yarden mandates a finding that his conclusion of no anticipation has no weight. Finally, it is noteworthy that Lipson *also* testified that calculating a deep tissue temperature when applied to the forehead, using an algorithm developed for an invasive thermometer (*i.e.*, the '397 algorithm), was "essentially what the FHT-1 did."[174]

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[173] *See Daubert*, 509 U.S. at 596 ("[I]n the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true, the court remains free to direct a judgment. . . ."). *Accord In re Joint Eastern & Southern District Asbestos Litig.*, 52 F.3d 1124, 1132 (2d Cir. 1995) ("The 'admissibility' and 'sufficiency' of scientific evidence necessitate different inquiries and involve different stakes. Admissibility entails a threshold inquiry over whether a certain piece of evidence ought to be admitted at trial. The *Daubert* opinion was primarily about admissibility. It focused on district courts' role in evaluating the methodology and the applicability of contested scientific evidence in admissibility decisions.") (citations omitted).

[174] Tr. (Lipson Rebuttal Cross) at 1536:5-17.

Likewise, no reasonable jury could have relied upon Yarden's contradictory testimony in finding no anticipation. Yarden's conclusion that the FHT-1 does not calculate a deep tissue temperature appears to be based on his unsupported testimony that, in the Appendix, T_{avg} is inputted into a polynomial formula in order to arrive at deep tissue temperature, and then the time-dependent parameters of temperature change (and one constant) are added to the result to correct to core.

As an initial matter, I note that "an inventor's subjective understanding of patent terminology is *irrelevant* to claim construction. . . ."[175] The reason for this rule is obvious: because the *quid pro quo* of receiving patent protection is public disclosure, an inventor's undisclosed thoughts have no bearing on construing a patent. Additionally, the inventor of a patent has every incentive to stretch the truth, further reducing the probative value of his uncorroborated testimony about his invention.

Although Yarden's unsupported testimony did not come in the context of *Markman* proceedings, it nevertheless falls within the scope of this rule, as his professed understanding of the Appendix is purely subjective. Yarden's testimony

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[175] *ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1321-22 (Fed. Cir. 2012) (emphasis added) (citing *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346-47 (Fed. Cir. 2008)).

is contradicted by the '668 Patent specification, which establishes that the output of the '397 algorithm is deep tissue temperature, while the entirety of the formula disclosed in the Appendix corrects to core.[176] It is also contradicted by Yarden's own deposition, in which he stated that the FHT-1 uses a third-order polynomial to correct to core.[177] In fact, even counsel for Medisim appear to have believed that

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[176] *See, e.g.* '668 Patent at col. 1:55-2:2 ("These temperature changes may be used to rapidly compute a deep tissue temperature of the body, using a heat flux calculation similar to that described in the ['397 Patent][,] for example."); *id*. at col. 2:6-11 ("The thermometer is configured to perform the heat flux calculation so as to derive a value of the local temperature. The local temperature, together with the temperature measurements and the time dependent parameters of temperature change may then be used to calculate a core body temperature."); *id*. at col. 7:1-17 ("The local temperature determined by the '397 algorithm is less affected than the surface temperature at the measurement site is to external factors such as ambient temperature and humidity. . . . In order to determine the core body temperature, processing unit 36 computes and applies an empirically-determined formula, which is described in detail in an Appendix herein below. The formula is based on fitting a linear equation comprising several temperature-related parameters to clinically measured values of core body temperature. The temperature related parameters include sensor temperature readings, time-dependent temperature rates of change, *and the value of local body temperature determined by the '397 algorithm*.") (emphasis added); *id*. at col. 12:43-49 ("wherein calculating the deep tissue temperature comprises estimating the deep tissue temperature by solving a time dependent heat conduction transfer equation, and wherein correcting for the difference between the core body temperature and the deep tissue temperature comprises computing a polynomial function of the deep tissue temperature.").

[177] *See* Goldberg Redirect at 1398:13-1399:18 (discussing the portion of Yarden's deposition that BestMed cited in opposition to Medisim's motion for summary judgment of no inequitable conduct, and pointing out the similarity between Yarden's description of the FHT-1 and the '668 Patent).

the formula disclosed in the Appendix described correcting to core.[178] In short, Yarden's unsupported, self-serving, and subjective characterization of the '668 Patent provides a legally insufficient basis for the jury's finding of no anticipation. Moreover, even if it could be credited, it still would not alter the necessary conclusion of no anticipation, because, as discussed above, the FHT-1 indisputably employs a third-order polynomial of the sort that Yarden claims is necessary for arriving at a deep tissue temperature.

For all these reasons, BestMed's motion for JMOL on anticipation is granted. The prior-art FHT-1 device meets the deep tissue temperature limitation of, and therefore anticipates, the '668 Patent. Because I direct JMOL on anticipation, I need not consider the parties' contentions on obviousness,

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[178] *See* Tr. (Medisim Opening Statement) at 57:8-13 ("For the FHT-1, you take the measurement and you directly calculate [an] approximation of core body temperature; whereas, . . . the '668 patent requires the two step process. You *directly measure* local or deep tissue temperature, and you correct in order to receive the core body temperature."). Counsel for Medisim altered this formulation during summations in a telling manner. *See id*. (Medisim Summation) at 1645:4-9 ("The '668 patent requires two steps: You measure *directly calculating* local deep tissue and then you correct to achieve an approximation of core. The FHT-1 is a one-step process, it directly takes you to core. It takes measurements and directly calculates an approximation of core body temperature."). What, if anything, "directly calculating" a value entails was left obscure. Needless to say, no reasonable jury could have found no anticipation based on the unsupported distinction between a "direct[]" calculation and an indirect calculation, particularly in light of undisputed evidence showing that the FHT-1 calculates an intermediate temperature using the '397 algorithm.

infringement, willful infringement, or patent damages.

B. Unjust Enrichment[179]

There is no evidence in the record to support the jury's award of damages to Medisim for unjust enrichment. The jury found against Medisim on its unfair competition claim, and was instructed that it could only find unjust enrichment based upon BestMed's sales of the accused products. To the extent that BestMed's sales of the accused products occurred during the operation of the IDA and the PSA, any claim for unjust enrichment is waived by those contracts.[180] Thus, the jury's verdict of unjust enrichment was grounded solely on BestMed's sales of the accused products subsequent to the termination of the PSA on May 1, 2009.

In light of my holding that the '668 Patent is invalid, and the jury's

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[179] I have considered, and reject Medisim's arguments that: (1) BestMed failed to preserve its motion for JMOL on unjust enrichment; and (2) BestMed's JMOL for unjust enrichment is an improper attempt to raise a Rule 12(b)(6) motion post-trial. *See* Opp. Mem. at 2-3; 23 n.30. *First*, BestMed moved for JMOL on unjust enrichment prior to the case's submission to the jury. *See* Tr. (JMOL Conference) at 1238:5-6. *Second*, BestMed's argument is that there is insufficient evidence to support the jury's verdict on unjust enrichment in light of the IDA and PSA, and the jury's verdict on unfair competition. This is a far cry from an untimely motion under Rule 12(b)(6).

[180] Medisim acknowledges that a claim for unjust enrichment that accrued during the IDA or PSA is waived, and argues that its claim for unjust enrichment accrued "when [BestMed] began selling the competing K-Jump device after the termination of both the IDA and PSA." Opp. Mem. at 23.

verdict of no unfair competition, an unjust enrichment claim cannot arise out of BestMed's sales of the accused products subsequent to the expiration of the PSA. Prior to the end of the PSA, Yarden applied for the '668 Patent, in hopes of receiving a limited monopoly in exchange for disclosing his invention to the public. Now that Medisim's attempt to gain a monopoly through the patent law has proved unavailing, it cannot argue that it should nevertheless receive the same protection through the state law of unjust enrichment.[181] A quasi-contract granting Medisim patent-like protection over its invalidated patent would usurp the federal patent law, and for this reason, the jury's verdict on unjust enrichment must be overturned.

Moreover, even if the '668 Patent were valid, there would be no basis in the record for the jury's award of damages on unjust enrichment, because there was no evidence to support a finding that BestMed received an incremental benefit over that compensable by the patent laws. Medisim did not present any evidence differentiating between patent damages and non-patent damages, instead relying

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[181] *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152-59 (1989) (holding that unpatentable subject matter, *e.g.*, an invalidated patent, passes to the public to freely use). *See also University of Colorado Found., Inc. v. American Cyanamid Co.*, 342 F.3d 1298, 1307 (Fed. Cir. 2003).

upon BestMed's profits from all of the accused products.[182] In its opposition brief, Medisim asserts that BestMed attained an incremental benefit over the benefit compensable through the patent law by its "misappropriat[ing] goodwill, improper[ly] us[ing] [] confidential know-how, and exploiting Medisim's information to start new customer relationships[,]"[183] but the only *evidence* it presents in support of this assertion relates to a single new customer of BestMed's, Kroger, who purchased the FHT-1 thermometer during the operation of the IDA.[184] For these reasons, I grant BestMed's motion for JMOL on unjust enrichment.

C. Medisim's Pending Motions

The following post-trial motions brought by Medisim are denied as moot as a result of the foregoing: (1) its motion for a judicial finding of willful infringement; (2) its motion for a permanent injunction enjoining BestMed from

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[182] *See* Tr. (Cross-Examination of Andrew Carter) at 995:23-996:9 ("A. Honestly, I don't know what non-patent claims are still in the case. I focused my work generally on the patent side. And on the non-patent side, [a] year and a half ago I calculated the profit on the BestMed units, and that's it. Q. Through this theory, this disgorgement theory of the non-patent damages, is that right? A. It's the profit of — it's the profit BestMed makes on its products, under whatever theory it comes in. I'm not trying to tie it off anyway. Again, I focused on the patent side, I merely calculated a profit number for the BestMed products. That's what I'm doing. I didn't get into all those other claims.").

[183] Opp. Mem. at 24 (citations omitted).

[184] *See* Tr. (Cohen Cross) at 706:1-9.

continuing its supposedly infringing activities; (3) its motion for interest and costs; and (4) its motion for an accounting of BestMed's pre-injunction sales and for supplemental damages.

Medisim's motion for sanctions and attorneys' fees is denied. Both parties engaged in 'zealous advocacy' throughout the case, and there is simply no basis in law or equity for exacting these extraordinary remedies on BestMed.

This leaves Medisim's motion for an injunction disposing of BestMed's infringing IFUs. Title 17 of the United States Code, Section 503(b) provides that a court may order

> [T]he destruction or other reasonable disposition of all copies . . . found to have been made or used in violation of the copyright owner's exclusive rights, and of all plates, molds, matrices, masters, tapes, film negatives, or other articles by means of which such copies or phonorecords may be reproduced.

As Medisim points out, it lacks a remedy at law for its copyright claim, leaving equitable relief as the sole remedy for enforcing its copyright.[185] For this reason, and because BestMed has not contested Medisim's right to equitable relief on its copyright claim despite having the opportunity to do so, Medisim's motion for a

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[185] Memorandum in Support of Motion for a Permanent Injunction and an Order for Disposition of Infringing Materials, Doc. No. 181, at 11 ("'An order directing impoundment or forfeiture is appropriate only where legal remedies or statutory damages do not provide adequate relief.'") (quoting *Software Freedom Conservancy, Inc. v. Best Buy Co.*, No. 09 Civ. 10155, 2010 WL 2985320, at *4 (S.D.N.Y. July 27, 2010)).

disposition of materials infringing its copyright is granted.

V. CONCLUSION

For the foregoing reasons, BestMed's motion for JMOL is granted. I hold that the '668 Patent is invalid as anticipated by the FHT-1 thermometer, and likewise overturn the jury's verdict for Medisim on its unjust enrichment claim.

Medisim's post-trial motions are denied, except for its motion for an injunction disposing of materials in BestMed's possession infringing its copyright, which is granted. BestMed is ordered to deliver all such infringing materials to Medisim within thirty days of this Order.

The Clerk of the Court is directed to close Doc. Nos. 130, 152, 177, 184, and 187. The Judgment entered at Doc. No. 156 is hereby vacated. The Judgment Clerk is directed to enter a new judgment consistent with this Order.

SO ORDERED:

Shira A. Scheindlin
U.S.D.J.

Dated: New York, New York
May 15, 2013

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